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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,649	08/01/2000	DANIEL LADANT	03495.0190	8848

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EXAMINER
ZEMAN, ROBERT A

ART UNIT PAPER NUMBER
1645

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,649

Applicant(s)

LADANT ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-15, 17-22, 25-32, 34-38, 46-59, 61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15, 17-22, 25-32, 34-38, 46-59, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-8-2003 has been entered.

The amendment filed on 10-8-2003 has been entered. Claims 10, 13-15, 17, 20-22, 25-32, 34-38, 46-49, 51-55 and 57-59 have been amended. Claims 1-9, 23-24, 33, 39-45 and 60 have been canceled. Claims 10-15, 17-22, 25-32, 34-38, 46-59 and 61-62 are pending and currently under examination.

Claim Rejections Withdrawn

The rejection of claims 10-15, 17-22, 25-32, 34-38 and 46-62 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fields et al. (U.S. Patent 5,468,614) is withdrawn in light of the amendment thereto.

The rejection of claims 10 and 25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "capable of" is withdrawn in light of the amendment thereto.

The rejection of claims 10, 13, 17, 21 and 25-38 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "interaction" is withdrawn in light of the amendment thereto.

The rejection of claims 20 and 36 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "gene with a selectable phenotype" is withdrawn in light of the amendment thereto.

The rejection of claims 22 and 38 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "performed in a bacterial strain" is withdrawn in light of the amendment thereto.

The rejection of claims 46 and 52 under 35 U.S.C. 112, second paragraph, for reciting improper Markush language is withdrawn in light of the amendment thereto.

The rejection of claims 49 and 55 for lacking antecedent basis for the limitation "color marker" is withdrawn in light of the amendment thereto.

The rejection of claims 51 and 57 for lacking antecedent basis for the limitation "the phage" is withdrawn in light of the amendment thereto.

The rejection of claim 59 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "bacterial cell" is withdrawn in light of the amendment thereto.

The rejection of claim 60 under 35 U.S.C. 112, second paragraph, as being vague and indefinite since it is dependent on a canceled claim is withdrawn. Cancellation of said claim has rendered the rejection moot.

Claim Rejections Maintained and New Grounds of Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 10-15, 17-22, 25-32, 34-38 and 46-59 and 61-62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-23 and 24-38 of copending Application No. 09/973013 is maintained for reasons of record. Applicant indicated that they intend to let this application go to allowance thereby obviating said rejection. The instant rejection will only be withdrawn when the instant claims are in condition for allowance **and** none of the cited claims in the copending application have been allowed. As stated previously, although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of selecting a molecule of interest that can bind to a target ligand (or identifying a substance that modulates said binding) utilizing signal amplification system comprising a bacterial multi-hybrid system utilizing enzyme fragments and/or enzyme modulators to detect protein-protein interactions. The instant claims are also drawn to methods wherein said selection is done in a bacterium.

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15, 17-22, 25-32, 34-38 and 46-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The methods recited in claims 10-22, 46-51 and 58 are rendered vague and indefinite as the lack essential steps. There is no correlation between the results (i.e. reconstitution of enzyme function resulting in activation of transcription) and the stated goal of selecting a molecule of interest. None of the rejected claims recite any "selection" steps.

Claim 1 is rendered vague and indefinite by the use of the phrase "triggering transcriptional activation". It is unclear what "gene" is being activated. Moreover it is unclear how the activation of said gene relates to the stated goal of the claim. Finally, it is unclear whether said activation is the end result of previous steps (i.e. signal amplification) or whether said activation is an independent step.

Claims 14 and 27 are rendered vague and indefinite by the use of the phrase "chosen from adenylate cyclase or guanylate cyclase and a modulating substance". It is unclear whether the modulating substance is a mandatory component of the first fragment or merely one of the possible options for the first fragment.

Claims 15 and 32 recite improper Markush language. When the phrase "selected from the group consisting of" is used, the penultimate member of the Markush group should be followed by the conjunction "and". It is unclear why Applicant amended the rejected claims since they previously recited proper Markush language.

Claim 17 is rendered vague and indefinite by the use of the phrase "binding between the molecule of interest and the target ligand is detected by signal amplification that triggers transcriptional activation and is **quantified by measuring the synthesis of a signaling molecule or expression of a reporter gene**". How is the synthesis of said signaling molecule measured? How is it correlated to the stated goal of the methods? Moreover, Claim 10 recites that step 4) is "triggering transcriptional activation". It is unclear what role this step would have in the claimed method if "binding" was measured by signal molecule synthesis.

Claims 20 and 36 are rendered vague and indefinite by the use of the phrase "protein with a selectable phenotype". It is unclear what is meant by the term phenotype as it is being applied to proteins since said term is generally applied to living organisms. Moreover, the specification does not disclose a definition of said term that would indicate it's meaning is other than that commonly accepted in the art.

The methods recited in claims 25-32, 34-38, 52-57, 59 and 61-62 are rendered vague and indefinite as they lack essential steps. There is no correlation between the results (i.e. reconstitution of enzyme function resulting in activation of transcription) and the stated goal of screening for a molecule that inhibits binding between a target ligand and a molecule of interest. It is unclear how one can determine activation or ablation of binding based on the application of a given "substance" when one abolishes transcriptional activation (Step 4).

Claim 25 is rendered vague and indefinite by the use of the phrase "triggering or abolishing transcriptional activation". It is unclear what "gene" is being activated. Moreover it is unclear how the activation of said gene relates to the stated goal of the claim. Finally, it is unclear whether said activation is the end result of previous steps (i.e. signal amplification) or whether said activation is an independent step.

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Claims 46 and 52 recite improper Markush language. It is unclear whether the term "fragment thereof" is referring to all the members of the Markush group or just the phage receptor protein.

Claims 48 and 54 recite the limitation "the reporter gene encodes resistance to an antibiotic" in line 2. There is insufficient antecedent basis for this limitation in the claim. Moreover, genes cannot "encode" antibiotic resistance. Genes encode for proteins that confer antibiotic resistance.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
December 18, 2003

L. F. Smith
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